Supreme Court, U.S.
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No. 97-1831

IN THE

Supreme Court of the United States

OCTOBER TERM, 1997

TEMPIE FORTSON WORTHY,

Petitioner,

v.

COLLAGEN CORPORATION,

Respondent.

On Petition for a Writ of Certiorari to the Supreme Court of Texas

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF FOR PETITIONER

The principal reason given by respondent Collagen Corporation for avoiding review is that this Court recently denied review on the same question. *See Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997), *cert. denied*, 118 S. Ct. 1300 (1998) (No. 97-1018). Petitioner does not, of course, know why the Court denied certiorari in *Mitchell*. But whatever the reason, it does not change the objective facts that favor review here: a deep split of authority in the lower appellate courts on an important issue of federal law—whether state-law damages suits involving medical devices that have received pre-market approval ("PMA") come within this Court's no-preemption ruling in *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996).

1. Respondent does not dispute that the question presented is important, and argues only that there is no meaningful conflict of appellate authority. In light of respondent's earlier efforts to obtain review on the same question as the one presented here (*see* Pet. 1), respondent's claim that there is uniformity in the lower courts is simply an attempt to avoid review of a decision favorable to it. As shown in the petition (at 12-16), the conflict among the state and federal appellate courts is substantial and will persist until this Court resolves the preemption issue.

Respondent asserts that the appellate decisions involving devices that have undergone PMA that are in conflict with the Texas Supreme Court's ruling are not from state supreme courts or from federal courts of appeals. Opp. 6. That argument is incorrect. In *Green v. Dolsky*, 685 A.2d 110 (Pa. 1996), *cert. denied*, 117 S. Ct. 1432 (1997), the Pennsylvania Supreme Court held that the PMA process preempts some product liability claims with respect to PMA devices, *but not other such claims*. Indeed, respondent filed a cross-petition in No. 96-1451, seeking a complete no-preemption ruling--like the one it obtained in the court below

in this case. *See Collagen Corp. v. Green*, 117 S. Ct. 1695 (1997).

Moreover, respondent is able to assert that the deep decisional conflict is limited to intermediate state appellate courts only by dismissing the post-*Medtronic* rulings in *Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997), and *Niehoff v. Surgidev*, 950 S.W.2d 816 (Ky. 1997), as involving different circumstances. But the rationales in those cases are flatly at odds with the opinion below. Although *Oja* did not involve a PMA device, it concerned a device for which the Food and Drug Administration ("FDA") had mandated a specific warning. The Tenth Circuit agreed with the defendant that the FDA-mandated warning was specific enough under *Medtronic* to be a preemptive federal "requirement." *Oja*, 111 F.3d at 789. It then held, however, that none of the plaintiff's claims were preempted, regardless of the specificity of the FDA requirement, because the plaintiff's "negligent failure to warn claim is predicated upon a general duty applicable to every manufacturer 'to inform users and purchasers of potentially dangerous items of the risks involved in their use.'" *Id.* (quoting *Medtronic*, 116 S. Ct. at 2258) (internal citations omitted)). Under the Tenth Circuit's reasoning, claims involving a medical device, including a PMA device, are not preempted under *Medtronic*, if damages are sought under general state-law duties applicable to other products in addition to devices. Thus, if petitioner's suit had been filed in the Tenth Circuit, it would survive preemption based on a rationale that cannot be squared with the Texas Supreme Court's ruling below.

The same is true of the Kentucky Supreme Court's decision in *Niehoff*, which concerned a class III medical device marketed under an investigational exemption. Like the Tenth Circuit in *Oja*, *Niehoff* held that none of the plaintiff's claims were preempted, regardless of the potential preemptive effect

of FDA regulations, because "Kentucky's strict liability case law and statutes [on which the plaintiff relied] are laws of general applicability to all products and fall beyond the scope of the federal preemption under [21 U.S.C.] §360k." *Niehoff*, 950 S.W.2d at 822. Thus, *Niehoff* makes clear that tort claims involving medical devices—including PMA devices—are not preempted under *Medtronic* if they are premised on state law of general applicability. *Id.*; *see Leslie v. Cincinnati Sub-Zero Prods., Inc.*, 961 S.W.2d 799 (Ky. App. 1998) (interpreting *Niehoff* and *Oja* in that manner).[1]

Respondent does not, because it cannot, challenge the precedential importance of the intermediate appellate rulings cited by petitioner, which hold that a grant of PMA does *not* trigger preemption under 21 U.S.C. 360k(a). Respondent does not deny that the rulings upon which the petition relies are binding in their geographical regions and would permit a suit identical to petitioner's to go forward in those jurisdictions.

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[1] Respondent's attempt to distinguish *Oja* and *Niehoff* is disingenuous at best. Indeed, in the paragraph immediately after respondent dismisses those cases, respondent relies on two federal appellate decisions because they involve, in respondent's words, "closely related circumstances" to those presented by the petition. *See* Opp. 6. But those decisions concern the *identical* issues as those involved in *Oja* and *Niehoff*, and come to diametrically opposed conclusions. *See Papike v. Tambrands, Inc.*, 107 F.3d 737 (9th Cir.) (same issue as before the Tenth Circuit in *Oja*, but taking opposite approach), *cert. denied*, 118 S. Ct. 166 (1997), and *Martin v. Telectronics Pacing System, Inc.*, 105 F.3d 1090 (6th Cir. 1997) (same issue as before the Kentucky Supreme Court in *Niehoff*, but taking opposite approach), *cert. denied*, 118 S. Ct. 850 (1998).

See, e.g., Kernats v. Smith Indus. Medical Sys., Inc., 669 N.E.2d 1300 (Ill. App.), *appeal denied*, 675 N.E.2d 634 (Ill. 1996); *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763 (Cal. App. 1996), *review denied*, 1997 Cal. Lexis 833 (Feb. 19, 1997); *Mears v. Marshall*, 944 P.2d 984, 993-95 (Ore. App. 1997), *review denied*, No. S44987 (Ore. June 2, 1998).[2]

Finally, respondent does not dispute the aspect of post-*Medtronic* confusion that best illustrates the practical consequences of allowing the conflict among appellate decisions to persist. Plaintiffs who file suit for injuries sustained from PMA devices in Illinois and Kentucky will receive different rulings on the critical preemption question depending on whether their cases are litigated in state or federal court. *Compare Kernats*, 669 N.E.2d 1300 (Illinois: no preemption), *with Mitchell*, 126 F.3d 902 (Seventh Circuit: complete preemption), and *Niehoff*, 950 S.W.2d 816 (Kentucky Supreme Court: no preemption), *with Martin*, 105 F.3d 1090 (Sixth Circuit: complete preemption). Similarly, in California, plaintiffs face preemption in one part of the state, but not in another. *Compare Armstrong*, 57 Cal. Rptr. 2d 763 (2nd appellate district: no preemption), *with Steele v. Collagen Corp.*, 63 Cal. Rptr. 879 (Ct. App. 1997) (3rd appellate district: preemption).

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[2] In *Mears*, a case involving a PMA device, the Oregon Supreme Court instructed the Oregon Court of Appeals to reevaluate its earlier pre-*Medtronic* no-preemption holding. *See Mears v. Marshall*, 921 P.2d 966 (Ore. 1996). Relying on *Medtronic*, the Oregon Court of Appeals again found no preemption, and on June 2, 1998, the Oregon Supreme Court denied review. *Mears v. Marshall*, No. S44987 (Ore. June 2, 1998).

2. Respondent suggests that review should be denied because the decision below is correct. Opp. 7-9. The issue at this stage, however, is not whether the preemption issue was handled properly below, but whether the Court should consider that issue at all, and on that score the confusion in the lower courts demands review. But if the merits of the Texas Supreme Court's decision were to enter into the certiorari calculus, petitioner has the better of the argument. *See* Pet. 16-20. Moreover, petitioner takes the same position on the merits as does the FDA, which recently explained to this Court its longstanding position that the Medical Device Amendments ("MDA") do not preempt damages claims involving injuries from devices that have obtained PMA. *See* Brief of the United States as Amicus Curiae in *Smith Indus. Medical Sys., Inc. v. Kernats*, No. 96-1405, at 14-18. That the agency charged by Congress with implementing the MDA believes that the decision below is incorrect underscores the need for review by this Court before petitioner's state-law rights to recovery—and the rights of similarly situated plaintiffs—are forever lost. *See Medtronic*, 116 S. Ct. at 2255-56 (deferring to FDA's preemption views); *id.* at 2261 (Breyer, J., concurring) (same).

CONCLUSION

For the reasons stated above and in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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